

MAR - 1 2004

**510(K) Summary****Submitter**

Name: Biocomposites Ltd  
Address: Etruscan Street  
Etruria  
Stoke on Trent  
ST1 5PQ  
England  
Tel No: +44 (0) 1782 206500  
Contact: Mr J. S. Bratt  
Date: 24th November 2003

**Name of Device**

Classification Name: Bone fixation fastener  
Common Name: Threaded Fixation Pin Bioresorbable ACL device  
Proprietary Name: BiLok® ST Screw

**Predicate Device**

Arthrex Bio Transfix cross pin K011172  
BiLok Screw K002070  
Biosteon Cross Pin K021351

**Device Function**

To hold a soft tissue graft in position during healing in the femoral bone tunnel.

**Device Design**

The cannulated BiLok® ST Screws are 6 – 9mm diameters and 30 – 40mm lengths.

**Materials Used**

The BiLok® ST Screw is moulded from a Poly L lactide/Beta Tri-Calcium Phosphate composite.

**Intended Use**

To hold a Semitendinosus ST or hamstring (soft tissue) graft in place in the femoral tunnel during the healing period following ACL reconstructive surgery.

**Substantial Equivalence**

The material of construction and methods of manufacture, packaging and sterilization of the BiLok® ST Screw are identical to the previously cleared BiLok Screw K002070

The function and indications for use of the BiLok® ST Screw are the same as for the Arthrex Bio Transfix Cross Pin K011172 and the Biosteon Cross Pin K021351.

The functional mechanical performance characteristics of the BiLok® ST Screw are equivalent to those of the Arthrex Bio Transfix Cross Pin and the Biosteon Cross Pin. Any differences between the BiLok Screw and the predicate devices do not raise any new questions regarding safety and effectiveness.

### **Indications for use**

Surgical reconstruction of anterior cruciate ligament (ACL) deficient knee to provide cross screw femoral fixation of the various soft tissue ACL autografts and allografts.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 1 2004

Mr. J. Stephen Bratt  
Managing Director  
Biocomposites Ltd.  
Etruscan Street, Etruria  
Stoke on Trent  
Staffordshire, ST1 5PQ  
United Kingdom

Re: K033792  
Trade/Device Name: BiLok® ST Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: November 24, 2003  
Received: December 5, 2003

Dear Mr. Bratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

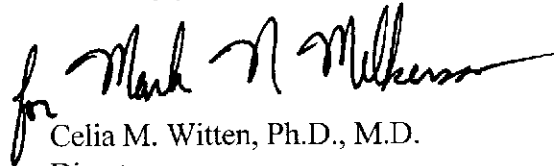
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. J. Stephen Bratt

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milken", is written over the typed name of Celia M. Witten.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033792

Device Name: BiLok® ST Screw

Indications For Use:

The BiLok® ST Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures.

The BiLok® ST Screw is used to provide suspensory fixation during femoral fixation in ACL reconstruction using a double looped (semitendinosus/gracilis) or quadruple (semitendinosus) graft.

Prescription Use Yes  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark A. Milheim*  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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